K010961

Ansell

PROFESSIONAL HEALTHCARE

MAY 31 2001

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X-Tenda Cuff® Powder Free Non-Sterile Latex Examination Gloves with Protein Content Labeling Claim (50 micrograms or less)
Ansell Healthcare Products Inc.
1875 Harsh Avenue SE
Massillon, Ohio 44646
Telephone: 330-833-2811
Fax: 330-833-6501

[1] Summary

[2] Ansell Healthcare Products Inc. Inc.
1875 Harsh Avenue SE
Massillon, Ohio 44646

Contact: James R. Chatterton
Telephone: 330-833-2811
Fax: 330-833-6501

March 28, 2001

[3] Trade Name: X-Tenda Cuff® Powder Free Non-Sterile Latex Examination Gloves with Protein Content
Labeling Claim (50 micrograms or less)
Common Name: Examination Gloves
Classification Name: Examination Glove

[4] X-Tenda Cuff® Powder Free Non-Sterile Latex Examination Gloves with Protein Content Labeling Claim (50 micrograms or less) meet all of the requirements of ASTM D 3578-00.

[5] X-Tenda Cuff® Powder Free Non-Sterile Latex Examination Gloves with Protein Content Labeling Claim (50 micrograms or less) meet all the current specifications for ASTM D 3578-00 Rubber Examination Gloves.

[6] X-Tenda Cuff® Powder Free Non-Sterile Latex Examination Gloves with Protein Content Labeling Claim (50 micrograms or less) are disposable devices intended for medical purposes that is worn on the examiners hand to prevent contamination between patient and examiner.

[7] X-Tenda Cuff® Powder Free Non-Sterile Latex Examination Gloves with Protein Content Labeling Claim (50 micrograms or less) are summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standard
Dimensions	Meets ASTM D 3578-00
Physical Properties	Meets ASTM D 3578-00
Freedom from holes	Meets ASTM D 3578-00 Meets ASTM D 5151-99

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Powder-Free	Meets ASTM D 3578-00 Not more than 2 mg residue by mass per glove.
Protein Label Claim	This latex glove contains 50 micrograms or less of total water extractable protein per gram.
Biocompatability	
Primary Skin Irritation in Rabbits	Passes
Guinea Pig Sensitization	Passes

[8] The performance test data of the non clinical tests are the same as mentioned immediately above.

[9] Clinical data is not needed for medical gloves or for most devices cleared by the 510(k) process.

[10] It is concluded that the X-Tenda Cuff® Powder Free Non-Sterile Latex Examination Gloves with Protein Content Labeling Claim (50 micrograms or less) (Modified) are as safe, as effective, and perform as well as the glove performance standards referenced above and therefore meet:

ASTM listed standards,
FDA hole requirements, and
labeling claims for the product.

[11] This summary will include any other information reasonably deemed necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2001

Mr. James R. Chatterton
Vice President of Regulatory
Ansell Healthcare Products, Incorporated
1875 Harsh Avenue, S.E.
Massillon, Ohio 44646-7199

Re: K010961
Trade/Device Name: X-Tenda Cuff Powder Free Non-Sterile Latex Examination Glove with Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 880.6250
Regulatory Class: I
Product Code: LYY
Dated: May 22, 2001
Received: May 23, 2001

Dear Mr. Chatterton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

X-Tenda Cuff® Powder Free Non-Sterile Latex Examination Gloves with Protein Content Labeling Claim (50 micrograms or less)

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Attachment 2

Indications for Use Statement

510(k) Number (if known) K010961

Device Name X-Tenda Cuff® Powder Free Non-Sterile Latex Examination Gloves with Protein Content Labeling Claim (50 micrograms or less)

Indications for Use X-Tenda Cuff® Powder Free Non-Sterile Latex Examination Gloves with Protein Content Labeling Claim (50 micrograms or less) intended for medical purposes that is worn on the examiners hand to prevent contamination between patient and examiner.

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010961

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
Per 21 CFR 801.109